IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

	X
	: : Civil Action No. 1:05-md-1661 (HB)(JCF) :
NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and PROTERRA AG, Plaintiffs,	USDC SDNY DOCUMENT ELECTRONICALLY FILED DOC #: DATE FILED: 1(Z D.5
v.	Civil Action No. 04-CV-06045 (HB)(JCF)
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	
Defendants.	· · «

EXCIPIENT SAMPLE STIPULATION AND ORDER

WHEREAS, plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG,
Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and Proterra AG (collectively,
"plaintiffs") have served Requests For The Production of Document and Things Nos. 64 and 65
("Request Nos. 64 & 65") on defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's
Laboratories, Inc. ("Reddy");

WHEREAS, Request Nos. 64 & 65 call for the production by Reddy of 50 grams from: (1) each batch of excipients used to manufacture every lot of capsules referred to in its Abbreviated New Drug Application ("ANDA"); and (2) each representative excipient batch;

WHEREAS, Reddy has objected to producing such excipient samples;

WHEREAS, plaintiffs on April 20, 2005 submitted to the Court a letter motion seeking, *inter alia*, production of such excipient samples;

WHEREAS, Reddy has offered a stipulation in lieu of production of said samples and to resolve this discovery dispute;

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED by and between the undersigned counsel for plaintiffs and Reddy:

- 1. Reddy agrees that in each of the rivastigmine capsule products that are the subject of its ANDA, the excipients will not in any way affect testing results concerning the amount of (S)-N-ethyl-N-methyl-3-(1-(dimethylamino)ethyl)-phenyl carbamate present in those products;
- 2. Reddy agrees that in each of the rivastigmine capsule products that are the subject of its ANDA, the excipients will not in any way affect testing results concerning the amount of (R)-N-ethyl-N-methyl-3-(1-(dimethylamino)ethyl)-phenyl carbamate present in those products;
- 3. Reddy agrees it will not argue, or otherwise submit evidence, that the excipients in the products that are the subject of its ANDA confound or otherwise affect testing results concerning the amount of (S)-N-ethyl-N-methyl-3-(1-(dimethylamino)ethyl)-phenyl carbamate present in those products;
- 4. Reddy agrees it will not argue, or otherwise submit evidence, that the excipients in the products that are the subject of its ANDA confound or otherwise affect testing results concerning the amount of (R)-N-ethyl-N-methyl-3-(1-(dimethylamino)ethyl)-phenyl carbamate present in those products;

- 5. Reddy agrees it will not argue, or otherwise submit evidence, in any way criticizing plaintiffs or experts retained on their behalf for not conducting testing on the excipients that will be used to manufacture the rivastigmine capsule products that are the subject of its ANDA;
- 6. Reddy agrees it will not argue, or otherwise submit evidence, in any way criticizing plaintiffs or experts retained on their behalf for conducting testing on samples of the excipients, that will be used to manufacture the rivastigmine capsule products that are the subject of its ANDA, independently obtained; and

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7. In view of Reddy's stipulations herein, Reddy no longer is required to produce any excipient samples to plaintiffs.

FITZPATRICK, CELLA, HARPER & SCINTO

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Dr. Reddy's Laboratories, Inc.

SO ORDERED Mounter this 216 day of October, 2005.

James C. Francis IV
United States Magistrate Judge